IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GLAXOSMITHKLINE LLC,	
Plaintiff,	**Civil Action No.** _____
v.	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,	
Defendant.	

COMPLAINT

INTRODUCTION

Plaintiff, GlaxoSmithKline LLC ("Plaintiff" or "GSK"), brings this complaint against defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Defendant" or "BI"). For its Complaint against BI, GSK alleges as follows:

1. GSK brings this suit to stop BI from communicating false and misleading information to healthcare providers on a matter of public health with serious economic consequences for GSK. In its promotion of its own competing product, BI is conveying false and misleading messages about GSK's ELLIPTA and DISKUS inhalers, which are prescribed to patients with Chronic Obstructive Pulmonary Disease ("COPD"). GSK seeks preliminary and permanent injunctive relief under the federal Lanham Act and state common law, as well as compensatory and enhanced damages and disgorgement of profits.

2. About 27 million Americans are currently diagnosed with COPD, an umbrella term used to describe progressive lung diseases including emphysema and chronic bronchitis. Many COPD patients obtain relief from their symptoms through inhaled medications.

3. GSK and BI are direct competitors for the prescription (and thus sales) of COPD medications. A key part of that competition is the device through which the COPD medication is administered. One such device is a dry powder inhaler. A very substantial number of COPD patients obtain relief from their symptoms by using GSK's highly regarded and well-established ELLIPTA and DISKUS dry powder inhalers. BI markets a newer to market, competing inhaler under the trade name RESPIMAT, which delivers medication through an aerosol mist.

4. In an effort to gain traction in the market for COPD medications, BI embarked on a promotional campaign for its RESPIMAT inhaler that falsely and misleadingly downplays the efficacy of the drug delivery achieved by GSK's ELLIPTA and DISKUS dry powder inhalers. Prior to bringing this action, GSK repeatedly addressed these false and misleading claims with BI. While BI was willing to modify some aspects of its marketing campaign, it has refused to revise or withdraw its core, false message: that many COPD patients will not receive adequate therapeutic benefit from GSK's ELLIPTA and DISKUS products. BI's message is belied by overwhelming clinical evidence. Nevertheless, BI has refused to make any further changes to its marketing campaign and has continued to make false and misleading statements about GSK's products.

PARTIES

5. GSK is a limited liability company organized under the laws of the State of Delaware and is a citizen of the State of Delaware.

6. Upon information and belief, BI is a corporation organized under the laws of the State of Delaware with a principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 1121 (Lanham Act jurisdiction) and 28 U.S.C. § 1331 (federal question jurisdiction). The Court has jurisdiction over GSK's common law unfair competition claim pursuant to 28 U.S.C. § 1367 (supplemental jurisdiction).

8. This Court has personal jurisdiction over BI because BI regularly conducts business and maintains continuous contacts in the Commonwealth of Pennsylvania, including in this judicial district, and including by promoting its RESPIMAT product and others, within this judicial district. Moreover, BI has communicated its false and misleading promotional messages in the Commonwealth of Pennsylvania, including in this judicial district.

9. Venue is proper in this judicial district pursuant 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in this judicial district.

FACTUAL ALLEGATIONS

10. COPD is a type of lung disease characterized by long-term breathing problems and poor airflow.

11. A Dry Powder Inhaler ("DPI") is a type of device used to administer COPD medication to patients. DPIs combine medication with dry inactive carrier particles. When a patient inhales through a DPI, the inhalation separates the medication from the carrier particles and delivers the medication to the lungs.

12. Many DPIs rely on the force of patient inhalation to separate the medication from the carrier particles. The force of inhalation is referred to as Peak Inspiratory Flow ("PIF") and is measured in liters per minute.

13. DPIs are an innovative improvement in the delivery of medication to treat COPD because the drug delivery is triggered by the patient's inhalation. By contrast, older aerosol

inhalers required the patient to time their inhalation to coincide with the release of the aerosol dispensing the medicine.

14. GSK markets two DPIs for the administration of COPD medication – DISKUS and ELLIPTA. The FDA approved, for marketing, ADVAIR DISKUS in 2000, ANORO ELLIPTA in 2013, BREO ELLIPTA in 2013, INCRUSE ELLIPTA in 2014, and TRELEGY ELIPTA in 2017. (The first name of each of these products is the GSK medication, and the second is the inhaler device.) Each of these products requires a medical prescription.

15. FDA labeling does not specify a minimum PIF required for medication delivered by DISKUS or ELLIPTA to be effective. Indeed, there is no clinical evidence demonstrating a link between PIF and the clinical efficacy of COPD medications.

16. BI markets COPD medications that are administered through RESPIMAT inhalers. RESPIMAT is not a DPI. Rather, RESPIMAT delivers medication through an inhalation spray.

17. The FDA approved SPIRIVA RESPIMAT in 2014 and STIOLTO RESPIMAT in 2015. Prior to RESPIMAT, BI marketed SPIRIVA in a DPI.

18. GSK and BI manufacture their products and then transport their products to market throughout the United States by highway, rail, or air. GSK's and BI's COPD inhalers are transported to and sold in the Eastern District of Pennsylvania and throughout the United States.

19. GSK and BI (and others) directly compete for the sale of COPD medications. A significant component of that competition is the inhaler through which the COPD medication is administered.

20. As part of that competition, GSK and BI market their products directly to healthcare providers, as do other pharmaceutical companies. GSK and BI market to healthcare

providers by, among other things, hosting educational presentations at conferences, sending direct mail and email communications, and conducting office detail visits.

21. During a detail visit, a pharmaceutical sales representative meets with a healthcare provider one on one at the healthcare provider's office. The sales representative often uses promotional materials, known as detail aids, to explain the therapeutic benefits of the company's products.

22. By the time BI began marketing the RESPIMAT inhaler, GSK's ELLIPTA and DISKUS inhalers had already earned strong reputations with healthcare providers that began with the medication and inhalers themselves, and which has been enhanced through GSK's extensive advertising, promotional, and educational efforts. ELLIPTA and DISKUS maintained their strong reputations after the launch of RESPIMAT drug products.

23. In an effort to gain a competitive advantage over DPIs in the COPD market, BI embarked on an aggressive false and misleading marketing campaign. The marketing campaign has included, among other things:

(a) distributing an editorial opinion regarding a clinical trial that evaluated TRELEGY ELLIPTA, which conduct did not meet the FDA standards for distribution of scientific and medical publications or for promotion;

(b) distributing a promotional piece with false claims regarding STIOLTO RESPIMAT's alleged superiority over ANORO ELLIPTA, claims which are not supported by a head-to-head study; and

(c) distributing a promotional piece with the false claim that fewer patients experienced COPD exacerbations when taking SPIRIVA RESPIMAT as compared to ANORO ELLIPTA.

24. Since BI launched RESPIMAT, GSK has repeatedly demanded in writing that BI stop using false and misleading promotional communications and practices to gain an economic advantage at the expense of accurate education of healthcare providers. Although BI sometimes

acquiesced to GSK's requests, BI has persistently pushed false and misleading messaging on healthcare providers to inflate its prescription drug sales.

25. In the summer of 2018, GSK learned that BI was widely distributing to healthcare providers a brochure for RESPIMAT (the "Brochure") that included false and misleading claims about DISKUS and ELLIPTA. The Brochure conveyed such false and misleading messages presumably to induce healthcare providers to prescribe RESPIMAT products when they would otherwise have prescribed DISKUS or ELLIPTA products.

26. The Brochure made the following false and/or misleading claims:

(a) more than half of COPD patients can have suboptimal peak inspiratory flow [PIF less than 60 liters per minute];

(b) even patients with mild COPD can have suboptimal PIF;

(c) 60% of patients with mild COPD failed to reach an adequate PIF for a high-resistance device;

(d) certain DPIs may require considerable inspiratory effort to activate optimally; and

(e) some DPIs require forceful inhalation to separate the medicine from the carrier particles.

27. In addition to the above false and/or misleading statements, the Brochure included:

(a) a chart that overstated the sample size of a cited study;

(b) images of DISKUS and ELLIPTA inhalers in yellow brackets suggesting that DISKUS and ELLIPTA were high-resistance devices that required considerable inspiratory effort to activate optimally; and

(c) a graphic suggesting that patients with suboptimal PIF would not be able to obtain any COPD medication from a DPI.

28. As a whole, the Brochure conveyed the message that the majority of COPD patients have suboptimal PIF and, therefore, do not receive therapeutically adequate medication

from ELLIPTA and DISKUS inhalers. The Brochure defined suboptimal PIF as less than 60 liters per minute.

29. By letter to BI dated September 18, 2018, GSK, through its undersigned counsel, addressed BI's continued false and misleading promotional efforts. GSK identified the false and misleading claims in the Brochure and demanded that BI immediately cease using the Brochure and any other promotional material that contained such false and misleading claims.

30. Over the course of the following nine months, GSK and BI exchanged an additional eight letters regarding the false and misleading claims in the Brochure as well as BI's other improper marketing activities.

31. Even though BI began using a revised Brochure in 2019 (the "2019 Brochure") that addressed some of the original version's problems, the 2019 Brochure still conveys the false and misleading message that patients with low or suboptimal PIF are unable to obtain adequate benefit from ELLIPTA and DISKUS inhalers.

32. The 2019 Brochure communicates its false and misleading message through, among other things, the following statements:

(a) many COPD inhalers may require patients to forcefully inhale to activate optimally;

(b) many COPD patients cannot forcefully inhale, yet many COPD inhalers require them to do so to activate optimally;

(c) up to 84% of COPD patients have a suboptimal PIF;

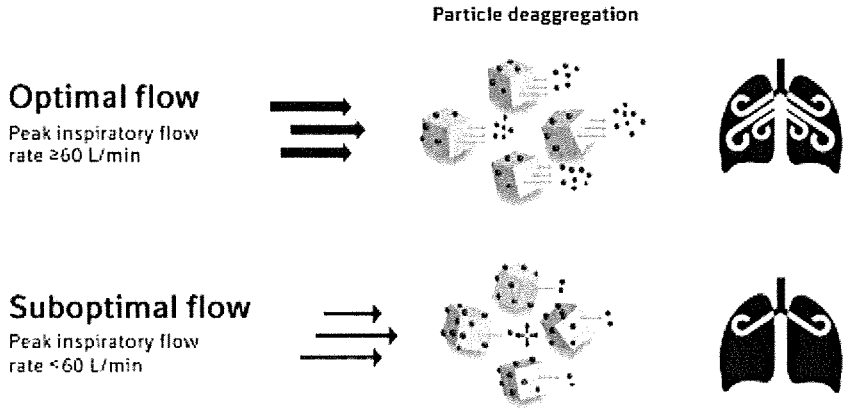
(d) more than one-third of commonly prescribed COPD inhalers require optimal PIF to activate optimally;

(e) even patients with mild COPD can have suboptimal peak inspiratory flow;

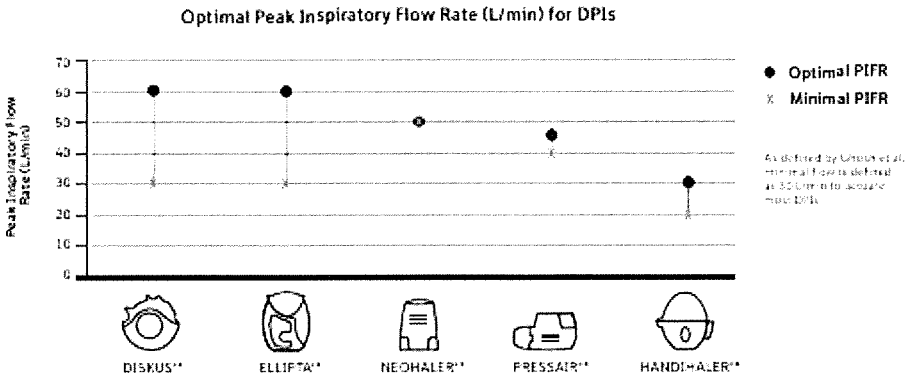
(f) some DPIs require forceful inhalation to separate medicine from the carrier particles; and

(g) certain DPIs may require considerable inspiratory effort to activate optimally.

33. BI's false and misleading message is reinforced by two graphics in the 2019 Brochure. The first graphic purports to show that COPD patients with suboptimal PIF cannot adequately separate medication from the carrier particles when using DPIs.



34. The second false and misleading graphic in the 2019 Brochure specifically includes images of DISKUS and ELLIPTA inhalers and claims that out of five DPIs, DISKUS and ELLIPTA require the highest PIF to activate optimally.



35. Thus, while BI made some cosmetic changes to the Brochure, BI's core false and misleading message remains intact.

36. The false and misleading messages conveyed by BI's 2019 Brochure are contradicted by the overwhelming clinical evidence of the efficacy of GSK's medications delivered via DISKUS and ELLIPTA for patients with moderate to very severe COPD.

37. *In vitro* studies measuring delivered dose through ELLIPTA at a PIF of 30 liters per minute showed that more than 85 to 90 percent of the target values were delivered for all component molecules.

38. Medical literature demonstrates that for DISKUS, there is not a significant difference in dose delivery between patients with a PIF of 30 liters per minute and patients with a PIF greater than 60 liters per minute.

39. For ELLIPTA, clinical studies have established that patients with very severe COPD were able to generate a PIF of at least 41.6 L/min, with a mean PIF ranging from 65.8 L/min to 67.5 L/min.

40. For DISKUS, clinical studies have established that patients with COPD and severely compromised lung function were able to generate a PIF of at least 46.1 L/min, with a mean PIF of 82.4 L/min.

41. Moreover, there is no clinical evidence demonstrating a link between PIF and the efficacy of COPD medications.

42. Upon concluding that BI would not further correct the messages contained in the Brochure, GSK, through an expert retained by counsel, conducted a survey to determine whether the messages communicated by the Brochure mislead healthcare providers about the therapeutic benefits of ELLIPTA and DISKUS (the "Survey").

43. The expert surveyed 331 healthcare providers including pulmonologists, internists, and general practitioners. The survey found that:

(a) 53% of healthcare providers understood that the 2019 Brochure communicated that the treatment of COPD patients with low or suboptimal PIF would be compromised by the use of a DPI;

(b) more than one-third of healthcare providers mentioned that some DPIs were less effective and/or might result in exacerbations or hospitalization for some patients with low or reduced PIF;

(c) 52% of healthcare providers stated that a GSK product was targeted by the 2019 Brochure;

(d) after reading the 2019 Brochure, 69% of healthcare providers believed that some of their COPD patients might need to switch inhalers; and

(e) healthcare providers believed that 26% of COPD patients might be inadequately managed by their current inhalers and potentially in need of another.

44. The Survey demonstrates that the messages contained in the 2019 Brochure are misleading because a majority of respondents received the incorrect message that patients with suboptimal PIF cannot use DPIs without some risk of clinical compromise.

45. BI's proprietary training materials for its personnel were also revised consistent with the insufficient changes BI made in the 2019 Brochure.

46. In addition to conveying false and misleading messages through the 2019 Brochure, BI has continued to communicate its false and misleading messages regarding DPIs through other promotional materials disseminated to health care providers. One example of BI's new promotional material includes a box that is labeled in big, bold letters, "Dry Powder Inhaler." Below the label, the wording on the box reads, "WARNING: Suboptimal Inhaler Included." Inside the box, BI includes a picture and figurine of a COPD patient. The message of this new promotional material is that COPD patients have suboptimal PIF and cannot use DPIs.

47. BI is also communicating false and misleading messages through an email newsletter sent directly to healthcare providers. The email newsletter communicates false and

misleading messages, consistent with those contained in the Brochures, through the following statements:

(a) "Many Patients with COPD Were Unable to Achieve a PIFR ≥60 L/min in Several Studies";

(b) "Even Patients with Mild COPD Can Have Suboptimal PIFR (<60 L/min)";

(c) "PIF is the first factor related to drug delivery from a DPI";

(d) "Lower flow rates may reduce the amount of drug delivered by a DPI";

(e) "Patients must inhale with enough force to overcome the inhaler's internal resistance, leading to deaggregation of the medication into fine particles that are more likely to be deposited into the peripheral lung"; and

(f) the email newsletter specifically lists the purported internal resistance required by ELLIPTA and DISKUS inhalers.

48. On September 27, 2019, BI communicated the same false and misleading messages at the American Academy of Family Physicians' annual conference in Philadelphia. The presentation to numerous health care providers communicated false and misleading messages, consistent with those contained in the Brochures, through the following statements:

(a) PIF below 60 liters per minute is "generally considered suboptimal";

(b) "With DPIs, inspiratory flow is dependent on the resistance of the device and the patient's inspiratory effort";

(c) "Some patients may not be able to achieve the correct inspiratory flow rate for optimal drug delivery";

(d) "When inhaling too slowly, the generated particles are too big to enter the lungs, increasing oropharyngeal impaction";

(e) For ELLIPTA and DISKUS, minimal PIF is 30 liters per minute and optimal PIF is 60 liters per minute; and

(f) "Suboptimal PIF is associated with hospital re-admissions."

49. During the presentation at the American Academy of Family Physicians' conference, the BI-paid presenter stated that DPIs might not work for patients with a PIF

between 30 and 60 liters per minute. The presenter stated that using a DPI with a PIF below 60 liters per minute is a "crap shoot."

50. BI representatives also engage in widespread false and misleading promotion of RESPIMAT by using the In-Check DIAL™ device during detail visits with healthcare providers. The In-Check DIAL is a hand held inspiratory flow measurement device. BI representatives are using the device to suggest falsely that patients with low PIF will be unable to receive COPD medication with ELLIPTA and DISKUS inhalers.

51. Specifically, BI's sales representatives are asking healthcare providers to inhale from the device while it is set to a significant resistance level that they claim is equivalent to the resistance a patient encounters when using the ELLIPTA inhaler. Upon information and belief, the BI sales representatives are grossly exaggerating the resistance level experience of an ELLIPTA inhaler.

52. BI has a large force of field representatives. BI has informed GSK that BI's internal training materials for its field representatives include the same messages and information that are contained in the 2019 Brochure.

53. BI's field representaitives, on information and belief, used the Brochure, and continue to use the 2019 Brochure, other promotional materials, and their training to communicate the 2019 Brochure's false and misleading promotional messages to healthcare providers across the country, causing GSK harm in the form of lost prescriptions and thereby lost sales.

54. The false and misleading claims contained in the 2019 Brochure and BI's other promotional materials and presentations are likely to cause GSK substantial and irreparable harm to its reputation and goodwill. RESPIMAT is a direct competitor of DISKUS and ELLIPTA,

and the Brochures specifically identify DISKUS and ELLIPTA by name and image. Moreover, the Survey demonstrates that: (i) the false and misleading messages contained in the 2019 Brochure have caused a majority of healthcare providers who treat COPD to believe that they might need to change the prescriptions of some of their COPD patients; and (ii) a majority of respondents specifically identified a GSK product as the subject of the false and misleading messages conveyed by the 2019 Brochure.

55. GSK will also sustain irreparable harm to its market share and sales given, as demonstrated by the Survey, the high probability of healthcare providers switching their patients from GSK to BI products due to BI's false and misleading messaging.

56. The risk of harm identified in the Survey is borne out by evidence in the field. Healthcare providers are increasingly telling GSK's sales representatives that PIF is important and that patients with a PIF below 60 L/min cannot use a DPI. GSK's sales representatives have observed that more and more healthcare providers are heeding BI's messaging and switching COPD patients from GSK's products to BI's RESPIMAT products, especially patients with more severe breathing difficulties. Once healthcare providers switch prescription habits it will be very difficult, if not impossible, for GSK to regain its lost market share.

57. GSK's market share and sales forecast for its DISKUS and ELLIPTA line of products further demonstrates the risk of irreparable harm posed by BI's false and misleading marketing campaign.

58. The public interest strongly favors imposing an immediate cessation of BI's false and misleading messaging to healthcare providers about DPIs approved for treating COPD.

COUNT ONE
LANHAM ACT, 15 U.S.C. § 1125(a):

59. GSK incorporates by reference the preceding paragraphs as though set forth fully herein.

60. BI has advertised and promoted RESPIMAT in interstate commerce in the United States by making false, deceptive, and/or misleading representations of the nature, characteristics, and qualities of DISKUS and ELLIPTA.

61. BI's RESPIMAT products compete with GSK's DISKUS and ELLIPTA products.

62. BI has made and is making explicitly and necessarily implicitly false, as well as misleading and deceptive, claims regarding the therapeutic efficacy of DISKUS and ELLIPTA.

63. BI's advertising has deceived and has a tendency to deceive and influence a substantial portion of its intended audience, including healthcare providers who treat COPD patients.

64. BI's false and misleading advertising is material because it is likely to influence healthcare providers' prescribing practices and habits.

65. Healthcare providers who treat COPD patients relied upon BI's false, deceptive, and misleading representations in prescribing BI's COPD medications.

66. BI's false and misleading representations have caused and will cause sales of COPD medications in interstate commerce to be diverted from GSK to BI.

67. BI's false, deceptive, and misleading representations of fact have caused and will continue to, imminently and into the future, cause substantial injury to GSK, including damage to GSK's sales and profits, business relationships, reputation, and goodwill.

68. BI's acts were willful, malicious, egregious, and in bad faith.

69. BI's false, deceptive, and misleading representations of fact violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

COUNT TWO
UNFAIR COMPETITION

70. GSK incorporates by reference the preceding paragraphs as though set forth fully herein.

71. BI has diverted business from GSK through the use of false and misleading advertisements regarding DISKUS and ELLIPTUS.

72. BI's actions violate general standards of fairness and social utility, and were calculated to procure an unfair competitive advantage over GSK.

73. BI's conduct has injured competition and deprived medical providers and COPD patients of accurate information about competing inhalers.

74. BI's continued publication of the 2019 Brochure and use of its false and misleading promotional messaging is willful and intentional.

75. The above-described conduct of BI constitutes unfair competition under common law.

76. As a direct and proximate result of these actions, GSK has been and is likely to be substantially and irreparable harmed in the damage to its reputation and goodwill and in the loss of its market share and sales.

77. GSK does not have an adequate remedy at law.

PRAYER FOR RELIEF

For the foregoing reasons, GSK prays for a judgment against BI as follows:

a. preliminarily and permanently enjoining BI from continuing to use and distribute the Brochures, and from disseminating any marketing materials, or otherwise conveying, orally or in any other manner, the false and misleading messages contained in the Brochures;

b. preliminarily and permanently enjoining BI from disseminating any marketing materials, or otherwise conveying, orally or in any other manner, that (1) patients with low, reduced, or suboptimal peak inspiratory flow (*i.e.*, less than 60 liters per minute) may not be able to use or activate dry powder inhalers; or that (2) patients with low, reduced, or suboptimal peak inspiratory flow (*i.e.*, less than 60 liters per minute) may not be able to receive a full or sufficient dose of medication from dry powder inhalers (the "Enjoined Marketing Claims");

c. ordering BI promptly to retrain its sales staff to ensure that the sales staff no longer communicates the false and misleading claims contained in the Brochures or the Enjoined Marketing Claims, and to certify to the Court when it has done so;

d. ordering BI promptly to recall all copies of the Brochures and other false or misleading promotional materials that contain the Enjoined Marketing Claims and that are currently in use or that have been distributed, and to certify to the Court when it has done so;

e. ordering an accounting and that judgment be rendered against BI for disgorgement of profits received from the sales of RESPIMAT products and that GSK be awarded such profits;

f. ordering BI to pay compensatory damages to GSK in an amount to be determined at trial, including GSK's lost profits, and damages for injury to the reputation and goodwill of GSK and DISKUS and ELLIPTA, which are attributable to BI's false and

misleading advertising and related actions that diverted sales of COPD medication from GSK to BI;

g. ordering BI to pay enhanced damages to GSK of treble the amount of compensatory damages due to BI's intentional, willful, deliberate, malicious, egregious, and bad faith actions, and to deter such actions in the future;

h. ordering BI to pay pre-judgment and post-judgment interest on the damages awarded;

i. ordering BI to publish appropriate corrective advertisements and statements;

j. ordering BI to pay GSK its costs in bringing this action, including reasonable attorneys' fees and expenses associated with bringing and prosecuting this action, including but not limited to the attorneys' fees available under the Lanham Act, 15 U.S.C. § 1117; and

k. awarding GSK such other and further relief as the Court finds to be in the interests of justice.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, GSK requests a trial by jury of any issues so triable by right.

Dated: _____

By: _____

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